DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

April 16, 2004

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 04-24

Mike A. Schoneveld, Owner
Country Side Dairy
771 Parklyn Way
Ferndale, Washington 98248

WARNING LETTER

Dear Mr. Schoneveld:

An investigation at your dairy located at 771 Parklyn Way Ferndale, Washington, conducted by a Food and Drug Administration (FDA) investigator on February 20 and 27, 2004, confirmed that you offered an animal for sale for slaughter as food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You also caused the adulteration of an animal drug because the drug was used in a manner that does not conform to its approved uses or the extralabel use regulations at Title 21, Code of Federal Regulations, Part 530 (21 CFR Part 530). This caused the drug to be unsafe under Section 512(a) of the Act and adulterated within the meaning of Section 501(a)(5) of the Act.

On or about, September 15, 2003, you sold a culled dairy cow, back tag #4266, identified on USDA-FSIS Lab Form #443915. This cow was sold for slaughter as human food to [redacted] who in turn sold the cow to [redacted] United States Department of Agriculture (USDA) analysis of a tissue sample collected from that cow identified the presence of penicillin at 0.07 parts per million (PPM) in the kidney. The established tolerance for residues of penicillin in kidney tissue is 0.05 PPM, 21 CFR 556.510. In addition, on or about September 16, 2003, you sold a culled dairy cow, back tag # 4320, identified on USDA-FSIS Lab Form # 443916. This cow was also sold to [redacted] who in turn sold the cow to [redacted] USDA analysis of a tissue sample collected from that cow identified the presence of sulfadimethoxine at 1.02 PPM in the liver and 0.57 PPM in the muscle tissue. The tolerance for sulfadimethoxine in edible tissue is 0.1 PPM, 21 CFR 556.640. The presence of penicillin and sulfadimethoxine above the established tolerance level in the edible tissues of these animals caused the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it

applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions that are inadequate to prevent animals bearing potentially harmful drug residues from entering the food supply. For example, our investigator noted the following conditions on your farm:

1. You lack an adequate system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.
2. You lack an adequate system for assuring that drugs are not used in a manner contrary to the directions contained in their approved labeling.

The investigation also determined that you adulterated an animal drug within the meaning of Section 501(a)(5) of the Act when you failed to use the drug in conformance with its approved conditions of use or the extralabel use regulations at 21 CFR Part 530. Specifically, you used the drugs penicillin and sulfadimethoxine in excess of the labeled dosage without a prescription for such use or you failed to withhold the animal from slaughter for the appropriate withdrawal times. Extralabel drug use is permitted only on the lawful order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship and in conformance with all other criteria set forth in 21 CFR Part 530, including that there may be no residue above established tolerance levels. Your use of penicillin and sulfadimethoxine failed to comply with the extralabel use regulations, causing the drugs to be unsafe under Section 512(a) of the Act and adulterated within the meaning of Section 501(a)(5) of the Act.

You should be aware that it is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal for sale that was shipped in interstate commerce to be slaughtered is sufficient to make you responsible for violations of the Act.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for sale for use as food, you are responsible for ensuring that your operations and the foods you distribute are in compliance with the law. You should take prompt action to correct the above violations and to establish procedures whereby such violations do not occur. Failure to do so may result in regulatory action, such as seizure and/or injunction, without further notice.

Please respond within fifteen (15) days of receipt of this letter and notify this office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed.

Please send your reply to the Food and Drug Administration, Attention: Bruce Williamson, Compliance Officer, 22201 23rd Drive SE, Bothell, WA 98021-4421. If you have questions regarding any issue in this letter, please contact Bruce Williamson at (425) 483-4976.

Sincerely,

Charles M. Breen
District Director

Enclosure:
Form FDA 483

cc w/copy of FDA-483:
Lael Alberg, DVM
Food Safety & Inspection Service
Western Regional Office
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Alameda, California 94501